# EXHIBIT H

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITY LITIGATION ) THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 2 OF MDL 200: Tamara Carter, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01661 ) Sandra Childress, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01564 ) Marion Chrysler v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02060 ) Melissa Sanders, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01562 Ana Sierra, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01819 ) Toni Hernandez v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02073 )

Master File No. 2:12-MD-02327 MDL 2327

) JOSEPH R. GOODWIN ) ) U.S. DISTRICT JUDGE

) PAUL J. MICHAELS, M.D. )
) JUNE 18, 2016

Reported by:

Rebecca J. Callow, CSR, RPR, CRR

Golkow Technologies, Inc. - 1.877.370.DEPS

	Page 2		Page 4
1		1	APPEARANCES:
2	DEPOSITION OF PAUL J. MICHAELS, M.D.	2	MII EMKANCES.
3	THIS DOCUMENT RELATES TO CARTER	3	FOR JOHNSON & JOHNSON AND ETHICON, INC.:
4	Austin, Texas	4	Thomas Combs & Spann PLLC
5	Saturday, June 18th, 2016	5	300 Summers Street
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13	Danny L. Curtis, P.C.	13	NO. DESCRIPTION PAGE
14	9229 Ward Parkway	14	Exhibit 1 Expert Report of Paul J. 6
15	Suite 370	15	Michaels, M.D. (Re: Tamara
16	Kansas City, Missouri 64114	16	Carter)
17	(816) 523-4667	17	Exhibit 2 09/28/2012 Pathology Report for 73
18	BY: Danny L. Curtis, Esquire	18	Tamara Carter
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2 (Pages 2 to 5)

Page 8 Page 6 1 PAUL J. MICHAELS, M.D., 1 A. I was asked to review her slide from her 2 Called as a witness herein, having been first 2 mesh excision and review her medical records and 3 duly sworn by a Notary Public, was examined and 3 basically write an expert report regarding my 4 testified as follows: 4 opinions with respect to both of those. 5 **EXAMINATION** 5 Q. How much time have you spent working on 6 BY MR. SNOWDEN: 6 Ms. Carter's case to date? 7 7 Q. Good morning, Dr. Michaels. A. I don't have that in hard copy with me. I A. Good morning. 8 8 would say over 20 hours, but not over 30. 9 Q. I'm Andy Snowden. I represent Ethicon in 9 Q. How much of that time was spent looking at 10 the case that we're talking about today. the pathology slide versus reviewing the other 10 11 Is it your understanding that we're materials? 11 going to talk about the Tamara Carter case? 12 12 A. I don't know exact numbers. Maybe 13 A. Yes. 13 reviewing the slide, photographing it, everything, 14 maybe when I add up all the time together, because I (Exhibit 1 marked.) 14 15 would look at it and then maybe come back to it 15 BY MR. SNOWDEN: 16 Q. I'm going to hand you what's been marked as 16 again to photograph it another time and look at it a Exhibit 1. Would you please take a look at that and 17 little more. Maybe over an hour, an hour-ish. 17 let me know if that contains your entire specific Q. And then the rest of that approximately 20 18 18 report regarding Tamara Carter. 19 hours was spent reviewing medical records. Is that 19 (Document review.) 20 right? 20 21 A. Yes. 21 A. Medical records and maybe reviewing 22 2.2 BY MR. SNOWDEN: literature regarding an issue I found in the case, 23 Q. And does the case-specific report in writing the report. That took a significant amount 24 Exhibit 1 contain all of your case-specific opinions of time. Discussions about the case. That would be Page 7 Page 9 for Tamara Carter? 1 mainly it. A. Yes. The caveat to that is since this, I 2 2 Q. Okay. Did you do anything to prepare for 3 have reviewed her deposition, but it didn't really 3 your case-specific deposition? 4 change any of my opinions in the case. A. I reviewed her deposition. Q. Do you have any additions or corrections to I reviewed my report again. 5 5 make to your report before we get started? 6 I reviewed some of the medical records 6 7 A. Well, I guess, the only thing I would say 7 again. Just very briefly went through the medical is after seeing her deposition, you know, it seems 8 8 records, not to the extent I did the first time. like her -- the number of pregnancies and deliveries 9 9 I reviewed the defense pathology 10 changed from one place to another. 10 expert report, and that was mainly it. 11 So I guess the only thing I would say 11 Q. Are you relying on any of the articles is that she's had multiple pregnancies that resulted 12 written by Dr. Iakovlev or any of his expert reports in multiple deliveries rather than saying four and 13 or depositions for any of your opinions in this 13 14 two and one. Just because it seems like that was 14 case? kind of all over the place. 15 15 A. Yes. Q. Okay. Which ones? Q. Okay. Does that have any effect on your, 16 16 any of your opinions in this case? 17 17 A. I would have to go through this list. 18 A. No. 18 (Document review.) A. I don't have all of the authors listed out. 19 Q. When were you first asked to work on the 19 20 Tamara Carter case? 20 There's some that he's listed as an author but it's 21 A. I don't have my -- oh, you know what? 21 not the first few. But basically, his article about 22 It would have been, I would say, 22 degradation of the mesh. 23 likely in March of this year. 23 BY MR. SNOWDEN: Q. Okay. What were you asked to do? 24 Q. Do you recall what year that was published? 24

3 (Pages 6 to 9)

Page 10 Page 12 1 A. I don't. 1 But I found that that's not uncommon 2 Q. Was that -- I'll strike that. in pathology where people refer to the same thing by 3 And I think you have an article -- a different names, and I assume that that's -- they literature reference, number 6. It's Bendavid, 4 4 were all talking about -- not assume, but they were 5 "A mechanism of mesh-related post-herniorrhaphy 5 all talking about the same thing, based on their 6 neuralgia." 6 diagrams and pictures. 7 7 Q. Are you relying on any other medical I believe that's a -- is it your understanding that's a Dr. Iakovlev article as well? 8 literature in this case that describes a -- and I'm 8 9 A. Yes, but there --9 using "bark" in quotes -- layer under the light 10 Sorry. I understood your question to microscope? 10 A. I don't remember if -- if it's been used in 11 say with regards to my opinions in this case, and 11 that article dealt with neuroproliferation. 12 12 other places. 13 Q. Okay. 13 Q. In this case, did you receive a gross A. And there wasn't any of that in this -- the 14 14 specimen? small amount of mesh that was in the slide. 15 15 A. No. 16 Q. Okay. Are you relying on any deposition 16 Q. And was your review -- and strike that. 17 testimony for your opinions in Ms. Tamara Carter's 17 How many specimens did you receive in case? Let me ask a better question. Sorry. 18 18 this case? 19 19 Are you relying on any of A. I just received one slide. 20 Dr. Iakovlev's deposition testimony for any of your 20 Q. Okay. And was that from the case-specific opinions here? 21 September 27th, 2012, excision surgery? 21 22 A. No. A. Yes. 22 23 Q. Are you relying on any of his expert 23 Q. Let's go to -- well, how did you make sure 24 that it was from that surgery when you first 24 reports in other litigation for your case-specific Page 11 Page 13 opinions in this case? reviewed the slide? 2 A. No. 2 A. The date on the slide, I think it was 2012, 3 Q. When did you first review Dr. Iakovlev's 3 and it correlated with the sheet that I received 4 degradation article? from the lab. A. A while ago. I don't -- I couldn't tell 5 5 Q. Other than review under the light you. Relatively early on in this -- in my 6 microscope and the use of polarized light 6 7 7 involvement with these cases. microscopy, did you do any other testing of any 8 Q. So that would have been prior to issuing 8 specimen for Ms. Carter? 9 9 this report in this case. Is that right? A. No. 10 A. Yes. 10 Q. If you could, turn to page 9 of your 11 Q. Is that where the term "bark," in your 11 report. You have, it looks like, an HNE picture at opinion, comes from? the bottom. Do you see that in your figures? 12 A. From where? 13 13 A. Yes. 14 Q. Does it come from Dr. Iakovlev's article 14 Q. Can you describe what we're seeing in that that you mentioned? 15 figure? And is this -- strike that. 15 A. I've seen it referenced in a few different Is this Figure 1? Because it's a 16 16 17 places. I don't know if that's the only place, that 17 little confusing because the headings are cut off 18 that's the origin of it. 18 from the page. Q. Okay. Do you recall any of those other A. Oh, yes. And it's Figure 1. 19 19

4 (Pages 10 to 13)

Q. So Figure 1 on page 9, please tell us

magnification view of a fragment of the mesh where

you can see the refractile polypropylene surrounded

A. So that is, I would say, a medium

20

22

23

21 what's depicted.

places where "bark" is referenced?

documentation regarding their studies.

A. I don't remember what Ethicon scientists

'80s or something when I reviewed those -- their own

called it. I know they addressed it as well in the

20

21

22

Page 14 Page 16 by dense fibrous tissue with chronic inflammation. 1 A. Could you repeat that? 2 Q. What kind of chronic inflammation is 2 O. Yeah. 3 3 present? In your practice, do you grade the 4 4 A. I don't know what you mean by what type degree of inflammation when it's present? of -- chronic inflammation: That's what it is. 5 A. In some types of specimens, yes. 6 Q. Okay. What type of cells do you consider 6 Q. Did you do that in this specimen? 7 7 in that -- being the chronic inflammation present A. No. This isn't one of the types that I 8 8 grade inflammation in. here? 9 A. I would say mostly lymphocytes, although 9 Q. Which types do you grade inflammation in? 10 there are likely some macrophages as well. A. Liver biopsies for hepatitis, you --10 there's a grading scale for inflammation. 11 Q. Are there any other foreign-body giant 11 Heart biopsies for acute allograft 12 cells present? 12 13 A. This magnification, I can't really tell. 13 rejection we grade inflammation. 14 Q. Do you recall finding foreign-body giant Same with kidney allograft rejection 14 cells in Ms. Carter's specimen? 15 15 we grade inflammation. 16 A. Yes. 16 You grade some inflammation in some 17 Q. Do you know how many you found? 17 types of non-neoplastic diseases of the colon, like A. I didn't count them. when you're evaluating for inflammatory bowel 18 Q. In Figure 1, could you ... disease like ulcerative colitis and Crohn's disease. 19 19 20 (Pause in proceedings.) 20 Same with celiac disease. In the 21 BY MR. SNOWDEN: 21 small intestine, we grade the types of inflammation Q. Could you, using that red pen, mark the 2.2 and the degree. 22 23 areas of chronic inflammation on Figure 1? 23 I would say those would be the main 24 A. By an arrow or circling, or how should I do specimens where, in the pathology report, it would Page 15 Page 17 it? 1 be important to issue some sort of statement 2 Q. Why don't you circle the areas of chronic 2 regarding the degree or severity of the 3 3 inflammation. inflammation. MR. AYLSTOCK: And, Doctor, you'll 4 Q. Is it important, then, when you're looking 5 want to put something under that because that marker 5 at a mesh removal to know the degree of 6 will bleed through. inflammation? 7 7 BY MR. SNOWDEN: A. Not as far as a grading system because 8 Q. Here. Why don't we use the red pen. 8 there's really not one that exists, to my knowledge, 9 9 (Witness complies.) that's used. 10 (Pause in proceedings.) 10 Q. Is there any way you differentiate between A. I would say I circled the main areas that I 11 what -- for instance, what you see in Ms. Carter's 11 can see at this magnification. case and other cases when it comes to degrees of 12 BY MR. SNOWDEN: inflammation? 13 13 14 Q. Okay. Did you find any -- well, is there 14 A. Just by looking at pictures, if I were to 15 any acute inflammation in Figure 1? compare pictures, I would say one has a more 15 16 16 (Document review.) significant degree of inflammation than the other. 17 This is certainly -- I would not 17 A. I don't think I saw any acute inflammation 18 in this specimen at all. 18 consider this minimal or slight, because that would just indicate just -- from a general pathologist's 19 So at this magnification it would be 19 standpoint, that kind of terminology would indicate 20 hard to ascertain the difference between them, so I 20 would say likely not. 21 a very few scattered lymphocytes or macrophages or 21 22 BY MR. SNOWDEN: 22 plasma cells that are not being clustered. 23 23 Q. Okay. In your practice, do you typically These are large groups of lymphocytes 24 that are, you know, adjacent to the mesh within the 24 grade the degree of inflammation in a specimen?

5 (Pages 14 to 17)

Paul J. Michaels, M.D. Page 20 Page 18 fibrous tissue, so I wouldn't come up with a term to that I brought with me. 1 grade them. I would just take a picture of it and 2 2 Q. Any that you can recall? 3 comment that there was chronic inflammation there. 3 A. Probably Robbins Patho -- or Robbins & Q. For all of your figures -- and you have six 4 Cotran, Enzinger and Weiss, Goldblum's book. Any 4 5 of them -- are you able to point to any nerve 5 soft tissue book, I'm sure, describes the presence 6 receptors? 6 of clefts within fibrosis tissue, both in a 7 7 A. Nerve receptors? non-neoplastic and neoplastic setting. 8 Q. Yes. 8 9 A. No. 9 gynecologic pathology texts? 10 A. Yeah. I would think so. Q. Do you have any nerves pictured in your 10 11 photos? 11 O. Are there -- are there authoritative 12 A. There are probably nerves on Figure 3, but 12 gynecologic pathology texts? it's a really low magnification view, and they are 13 A. There are several gynecologic pathology 13 not within the fibrosis of the mesh, so I didn't 14 14 texts? 15 comment on them. 15 16 Q. Let's go to Figure 3. 16 the past or continue to use? 17 17 A. There are several. A. Okay. 18 Q. You said there are probably some -- and 18 Q. Any in particular? 19 just tell me if I'm wrong here. 19 A. Dr. Young's book. There are probably some nerves, but 20 20 21 they're not in the fibrosis of the mesh in Figure 3. 21 the two main ones. Where does the fibrosis of the mesh 2.2 22 23 stop in Figure 3? 23 24 A. Do you want me to draw it? book. That's a good book. Page 19 1 Q. Yes. If you want to draw a line. 1 2 A. I would say the scar plate is pretty --2 Anyone else? 3 this is actually a really good case, because you can 3 A. Well, if you know anything about books, you clearly see this rounded encapsulating fibrosis 4 5 5 which is described in the literature with regards to aren't at Harvard. 6 Q. Okay. Blaustein's "Pathology of the 6 these. So ... 7 7 Q. So you've drawn an oval around the area of Female" --8 fibrosis. 8 A. I don't -- I've never liked that book. 9

- 9 A. Yeah. I may -- there may be a little bit 10 that extends up to here, but the actual sclerotic -where you can see the clefting of the fibrosis is 11 12 pretty clear around here and extends a little up 13 there.
- 14 Q. How do you differentiate between clefting of fibrosis versus the presence of loose connective 15 16
- 17 A. Pathology residency.

24

18 Clefting is a microscopic finding that you look at and you say there are clefts between the 19 tissue. It's not really -- you don't see that in normal, loose -- loose fibrosis tissue. 21

- 22 Q. Are there any books we can look at that 23 would show us that?
  - A. Probably any general pathology book. Not

- Q. Would something like that be found in
- Q. Okay. Are there any that you have used in
  - Christopher Crum's book. Those are

Some people use Robboy. I don't tend

to use that one very much. Olivi and Nucci have a

Page 21

- Q. So far you've only named people at Harvard.
- know that they have chapters written by people that
  - Q. Okay. Why not?
- 10 A. I don't like the way it's written. It has
- 11 a lot of not useless information, but it just
- seems -- it's not very helpful from a pathologist's
- standpoint. Most people that I've worked with don't 13
- 14 use that very much.
- 15 I mean, it's obviously a big textbook,
- 16 but I personally -- you're asking about what I use.
- 17 I don't use that.
- 18 So WHO for, you know, ovary and cervix and uterus. That's the international book. So 19
- 20 those would be the main ones.
  - O. Okay.
- 22 A. The Fascicles. The AFIP Fascicles.
- Q. Are those books that you've mentioned
- 24 typically written by leaders in the field -- sorry.

6 (Pages 18 to 21)

21

Page 22 Page 24 1 to your opinion. 1 Let me start over. 2 Are the chapters in those books 2 A. No. I don't grade the degree. So I don't 3 typically written by leaders in the field? 3 say -- you were asking initially about grading, and 4 A. No. I wouldn't say so. Not typically. 4 I said that I don't grade the degree of 5 I mean, they're written by people 5 inflammation. 6 that -- the editors who are the leaders in the field 6 But noticing the quantity without 7 7 will say, "Hey, do you want to write a chapter on placing a grade on it is something that you do when 8 you compare from one to another. 8 such-and-such?" 9 "Okay. I'll write a chapter on 9 Q. Okay. The quantity of inflammation in 10 Ms. Tamara Carter's case, how does that compare to such-and-such." 10 11 And then it will be reviewed and 11 other cases? 12 edited by the leaders in the field, but not taking 12 A. I would have to see the picture of it to anything away from the people that have written show you how it compares. 13 13 Q. Okay. Is this -- is this a slight 14 chapters whatsoever. 14 reaction, a moderate reaction, a marked reaction, or 15 But I wouldn't say that because 15 16 someone has a chapter in a book it anoints them as a 16 you just wouldn't place a grade on it? 17 17 MR. CURTIS: Object to the form of the leader in the field. 18 Q. If you take a look at Figure 2 -- actually, 18 auestion. 19 before we move to Figure 2, where in the body did 19 A. I would say it's somewhat moderate based on Figure 1 come from? 20 20 this picture. 21 21 A. I think it came from the posterior vaginal BY MR. SNOWDEN: wall, to my recollection. That's what it was 2.2 22 Q. Okay. And that's -- based on Figure 1 23 reported to have come from. 23 that's moderate inflammation. 24 Q. All right. Do you know where in the 24 A. Well, I mean, again, like I said, I'm Page 23 Page 25 posterior vaginal wall? not -- I'm not grading it. So I'm saying it's -- you know, it's a 2 A. I couldn't point to a location. 2 3 Q. What significance to your opinion in this 3 good amount of -- it's not slight, it's not all over 4 case is the inflammation seen in Figure 1? the tissue. And you're not going to force me to 5 5 A. I guess I don't -- can you repeat that? grade it when I'm telling you that I don't grade 6 6 Q. I'll ask a better question. them, so ... 7 7 Do you place any significance to your Q. Okay. So what significance does the degree 8 8 finding of chronic inflammation? of inflammation have on your opinion in this case? 9 9 A. Well, I evaluate all of the findings MR. CURTIS: I know it was not 10 together. So it's not just that there is chronic 10 intentional, but you've cut him off a couple of inflammation, it's the degree of chronic 11 11 times. Would you please wait until the doctor inflammation, the location of the chronic 12 12 finishes his answer. inflammation, exquisitely surrounding the mesh. Its 13 13 MR. SNOWDEN: Sure. 14 location within the dense fibrosis that's 14 THE WITNESS: Can you repeat that? 15 surrounding the mesh. 15 THE REPORTER: Yes. (The record was read as requested: 16 So it's more than just, for me, seeing 16 "So what significance does the degree 17 that there's chronic inflammation, it's knowing 17 18 where it is in the biopsy and what it's intimately 18 of inflammation have on your opinion associated with, which in this case is the mesh, 19 19 in this case?") MR. CURTIS: What was his answer? 20 which shows that there is significant inflammatory 20 reaction to the mesh in this patient. 21 21 Do you need to hear part of the answer 22 Q. Okay. Earlier you told me you don't 22 that you gave? 23 typically label the degree of inflammation and you THE WITNESS: No. That's fine. just told me the degree of inflammation is important 24 A. I would say it supports my opinions.

7 (Pages 22 to 25)

Page 26 Page 28 BY MR. SNOWDEN: 1 BY MR. SNOWDEN: 1 2 Q. How does it support your opinions? 2 Q. Okay. Is it your testimony that it's not 3 A. Because it's showing that there is an 3 common in the field of pathology to rate or put a 4 inflammatory response to the mesh. 4 degree on inflammation? 5 Q. Okay. Does it matter for your opinions --5 A. Okay. So we can go over this again, but 6 strike that. 6 there are certain locations in the body and certain 7 7 Does the degree of the inflammation diseases where you do grade inflammation routinely. 8 matter for your opinions? Now, when you're looking at a vaginal 8 9 A. Well, if there was just one lymphocyte or 9 mesh erosion that is taken out with fibrous tissue, two lymphocytes, I wouldn't comment on that. So the then we don't typically grade them with a numerical 10 10 fact that I'm commenting on inflammation means that 11 score. I'm considering it pathologic in this case, which I 12 12 In this case, what I do is I described 13 13 that there was chronic inflammation. And I took 14 Q. And at what point do you consider it 14 pictures to demonstrate the chronic inflammation so 15 pathologic? that at trial when I'm describing this, I can show A. There's no way for me to really count the 16 16 the number of inflammatory cells and how they're 17 number of lymphocytes as we sit here and tell you 17 surrounding the mesh and present within this scar how many wouldn't be. fibrosis tissue. 18 18 19 I can tell you from this tissue 19 Q. So how many inflammatory cells did you 20 removed from this client, Ms. Carter, that this is 20 count? significant, and that's what I would say and that's 21 21 A. I didn't count them. I wouldn't have. what I did say in here. 22 22 That's not a standard. 23 Q. But in this case you're not using a grading 23 Q. That's part of your answer, though. We'll 24 move on. 24 system. Right? Page 27 Page 29 1 1 A. Right. MR. CURTIS: Just a minute. Just a 2 We don't -- I don't use -- none of us minute. 3 use grading systems for --3 MR. THOMAS: Let's get an even keel 4 Q. And --4 here. A. Don't. Stop cutting me off. 5 5 MR. CURTIS: Refrain from making 6 Q. I -- actually, I haven't said anything. 6 remarks that are not a question. It's just not 7 A. Yeah. You were starting to talk. 7 appropriate for you to editorialize about the 8 So, as I said, we don't use grading 8 answers that you don't like, and we're not going to 9 systems. I'm not doing a study. So in studies they 10 may say grade 0, 1, 2, 3. We don't do that when 10 MR. SNOWDEN: And I'd ask that that go 11 both ways. evaluating these types of specimens, we would just 11 comment on whether there's inflammation present. 12 MR. CURTIS: But it starts with you. And in this case I took pictures of it to 13 Because you're not going to antagonize this witness. 13 14 demonstrate that morphologically. 14 MR. SNOWDEN: You're wasting my time. 15 Q. So do we just have to take your word for 15 MR. CURTIS: Just change your what level it becomes significant? attitude. You came in here with some burr up your 16 16 MR. CURTIS: Object to the form of the 17 17 ass. I don't know what it is, but settle down and 18 18 ask your questions -question. 19 A. I took pictures. So no. You don't have to 19 MR. THOMAS: Let's go off the record. 20 MR. SNOWDEN: Let's go off the record. 20 take my word for it, because I took pictures. 21 So, by definition, it's not just my 21 (Discussion off the record.) word, it's an image demonstrating what I've 22 BY MR. SNOWDEN: 22 described. 23 Q. All right. Dr. Michaels, if you could turn 24 24 to Figure 2 of your report. ///

8 (Pages 26 to 29)

Page 30 Page 32 Could you please tell us what we see fibrosis and has fibrosis between the filaments, and 1 1 2 here in this photo? 2 there's associated inflammation around those 3 3 A. So in this photo there are mesh spaces individual filaments. towards the left of the photo with a little bit of 4 And then the upper part of the figure mesh that's still in there on the bottom left. 5 5 shows more -- shows the adjacent stroma within the 6 And there's -- excuse me -- chronic 6 specimen that has -- you can see the obvious --7 7 well, you can see blood vessels in the upper part inflammation with lymphocytes and macrophages, and 8 there's some multinucleated foreign-body giant with some of the more edematous -- I should say not 8 9 cells, there's some dilated blood vessels, and there 9 edematous, but loosely -- loose stroma. are areas of fibrosis at the upper right and lower 10 Q. Did you -- I think earlier we talked 10 right periphery of the figure. 11 11 about -- you drew a circle on the figure and you 12 Q. Okay. The figure legend says, said this was the encapsulated scar. Did you 12 13 "Granulomatous tissue reaction associated with measure the thickness of the encapsulated scar in 13 14 adjacent mesh filaments." 14 this case? Do you see that? 15 15 A. No. I didn't measure the thickness of the A. Yes. 16 16 encapsulating scar in this case. 17 Q. What makes this granulomatous? 17 Q. Does that have any impact on your opinions? A. The fact that there are foreign body-type A. No. It doesn't have an impact on my 18 18 19 giant cells and histiocytes. 19 opinions. 20 Q. What significance, if any, does the 20 Q. Why not? 21 presence of granulomatous tissue have on your 21 A. Because it matters that it's there, not the 22 opinion in this case? 2.2 size of it. 23 A. Well, it's showing that there's a reaction 23 Q. Did you measure the distance from the mesh 24 to the foreign material present within the specimen. 24 to -- well, let me start over. Page 31 Page 33 Q. Do you grade the degree of granulomatous 1 Outside of the circled area on Figure 3 2 inflammation? that you've put on the exhibit, is the tissue --3 A. No. 3 would you call it normal? 4 4 Q. Anything else of significance in Figure 2? A. It appears unremarkable --A. I think I just described basically the 5 5 Q. Okay. whole figure, so in that -- I guess, in this 6 A. -- from this magnification. 6 7 particular objective, that would be what I would 7 Q. All right. Did you measure the distance from the mesh fibers to unremarkable tissue in this 8 describe from it. 8 9 9 Q. Turn to -- well, before we do that, did you case? 10 measure the thickness of the granulomatous 10 A. No. inflammation in this case? 11 Q. Does it matter to your opinions? 11 A. No. I didn't quantify or measure the 12 12 A. No. thickness of the granulomatous inflammation. 13 Q. Why not? 13 A. Because what is in the mesh is abnormal. 14 Q. Does that have any impact on your opinions 14 in this case, the thickness of the granulomatous So it's not like they need to excise -- it's not 15 16 inflammation? like a tumor, that it's malignant and you have to 16 measure how close the tumor is to the resected 17 17 A. No. 18 Q. Does it just matter that it's there? 18 margin. A. That it's there and that it's quite 19 19 There's no need to measure anything. 20 visible, and the location of it. 20 Just because there's normal tissue adjacent to the 21 Q. Okay. Let's go to Figure 3. What do we 21 mesh means nothing from this -- the distance. 22 see in this photomicrograph? 22 Q. Figure 4 in your report: Is this a higher A. So towards the bottom of the tissue piece 23 magnification of the bottom portion from Figure 3? 23 24 there is a portion of mesh that's surrounded by 24 A. Yes.

9 (Pages 30 to 33)

Page 34

1 Q. What are we looking at in Figure 4?

A. We are looking at the fibrosis between the two areas of mesh filaments, and we're also seeing the clefting of the fibrosis tissue, which you just see when you have sclerotic scar tissue basically, or fibrous tissue.

And then you can also see that each of those mesh filaments is surrounded by a chronic inflammatory response. And then we know from the prior one -- one of the prior figures that there is evidence of a granulomatous response with the foreign-type giant cells.

Q. Did you -- well ...

14 And then Figure 5: Is that an even higher magnification of the middle portion of 15 Figure 4? 16

A. Yes.

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18 Q. Do you have an opinion in this case 19 regarding whether Ms. Carter's mesh contracted in 20 her body?

21 A. Yes. I would say that based on these 22 findings it appears that it -- it would have.

23 Q. And which findings specifically are you 24 referring to?

for that opinion?

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A. My kind of career of reading medical literature. It's not like it's only been described in one location. I'd say "Oh, yeah. So-and-so mentioned it in 1995."

Page 36

Page 37

It's just kind of a general -- it's a general. It's general knowledge. Pathology knowledge.

Q. Did you measure the pore space in Ms. Carter's specimen?

A. No.

12 Q. Do you know whether you saw a pore in the 13 tissue specimen?

14 A. Well, I didn't examine the gross tissue 15 specimen.

Q. Are we looking at a pore in Figure 4? 16

17 A. That's the space between it. Correct.

Q. And so --

A. This is -- this would be deformed, 19

20 technically. I mean, it's a different area. 21

This whole area is sort of deformed 2.2 because it shouldn't just have -- you have clusters

of filaments here, so it's kind of indicative of the

fact that it's sort of deformed.

Page 35

A. The encapsulating fibrosis would probably be -- I would say the most suggestive finding to correlate histologically at least, because that's what you typically see in any aspect of the body when you have scar tissue. When it's surrounding a

structure, that's when you have that kind of shrinkage or contracture.

So I would say that that would be the histological correlate to a contracture.

Q. And what -- what's the basis for your opinion that the presence of fibrosis is a histological correlate for contracture?

13 A. My entire, I guess, experience as a 14 pathologist, that that's -- and my reading. That's 15 what you see with contractures is, you see dense fibrosis. You see a fibrous scar.

16 17 Whether it's a contracture in 18 someone's hand or vaginal region or something in the abdomen, that's -- the histologic correlate is 19 20 usually dense hyalinized cellular fibrosis. 21 Q. Is that found in any medical literature

22 anywhere?

23 A. Yeah. Everywhere.

Q. Are you relying on any medical literature

Q. Okay. Take me through next -- I don't understand why --

3 Why do the clusters of fibers mean it's 4 deformed?

A. Well, you can see that this is -- it's not uniform. So you have like four -- on the right you have four filaments spaces, where on the left you have six and they're at different spacing.

So normally, when you would have the mesh prior to implantation, everything would be uniformly spaced. But in here, you can see, based on its incorporation into the tissue, that it's not.

13 So I'm using that to say that it's, by definition, 14 not the same form, so it's deformed.

Q. Have you sectioned the pristine mesh and 15 looked at it under a microscope? 16

17 A. Like unremarkable mesh?

18 Q. No. Pristine mesh out of the box.

A. No. 19

20 Q. Have you ever seen a TVT out of the box?

A. Under the microscope?

22 Q. Under the microscope or just in person.

23 Have you had one in your hands?

24 A. Yes.

10 (Pages 34 to 37)

Page 40 Page 38 BY MR. SNOWDEN: 1 Q. When was that? 1 2 A. In medical school or probably towards the 2 Q. You can answer. 3 3 end of medical school. A. Yeah. It's like a crisscross. Q. Have you ever had a Prolift in your hands? 4 So, I mean, I'm not a good drawer, but 4 A. I don't recall if I've ever had a non-used 5 5 I've seen it; I've held it in my hands, as I've 6 Prolift in my hands. 6 already testified, but -- and I've seen the 7 7 difference between anterior and posterior in the Q. Okay. If I asked you to -- and I'm not 8 Total Prolift, so I -- I could -- you know, I know 8 asking at this point, but would you be able to draw 9 the structure of a Prolift? 9 what that looks like as well, so ... 10 Q. And this is my last question on this. MR. CURTIS: Object to the form of the 10 11 How many filaments surround a Prolift 11 question. 12 MR. AYLSTOCK: And I would also say 12 pore? this is -- I don't know, this is general 13 13 A. I'm not --14 MR. CURTIS: I object to the form of 14 questioning. 15 15 MR. CURTIS: Yeah. the question. 16 MR. AYLSTOCK: We're really far afield 16 Go ahead. of Ms. Carter and you're -- and his case-specific 17 A. I would have to look at a picture of it. 17 18 18 opinions in this case. So we provided ample BY MR. SNOWDEN: 19 Q. Did you do that before coming to your 19 opportunity for general questioning, that deposition 20 is closed. 20 opinion that Figure 4 shows deformation of the mesh? 21 MR. SNOWDEN: And I'll have to 21 A. Could you repeat that? 22 O. Yeah. 22 respectfully disagree with you. Dr. Michaels just testified that as part of this case he can tell it's 23 Did you look at a picture of a Prolift deformed based on the structure, and I'm trying to 24 before coming to the opinion in Figure 4 that the Page 39 Page 41 figure out what the basis for that opinion is. mesh was deformed? 2 BY MR. SNOWDEN: 2 A. Yes. I've seen the pictures before I came 3 Q. So, Doctor, if I asked you to -- and I'm 3 to that conclusion. not right this second -- would you be able to draw 4 Q. Is there any blood vessels in Figure 4? 5 A. Yes. 5 the filament structure of a Prolift? 6 6 MR. CURTIS: We object to the form of Q. So would you agree this tissue is 7 7 the question. And I can tell you that we're not vascularized? 8 going to engage in any drawing of the --8 A. I would say the tissue in Figure 4 is 9 9 MR. SNOWDEN: I haven't asked him to. vascularized. 10 MR. AYLSTOCK: And are you talking 10 Q. Is there any edema present in Figure 4? about the outline of the mesh or --11 A. It's hard to tell at this magnification for 11 THE WITNESS: Yeah. I don't 12 12 certain. 13 13 Q. Figure 4 captures every single mesh understand. 14 filament from Ms. Carter's body that you have MR. AYLSTOCK: The whole thing is 14 reviewed. Correct? 15 confusing. 15 BY MR. SNOWDEN: 16 A. I believe so. 16 17 Q. If I asked you to draw a pore with the 17 Q. Okay. And so if we count them, it's a 18 total of 10. Is that right? 18 outlining mesh filaments, could you do it? A. Yes. 19 MR. CURTIS: I continue to object to 19 20 the form of the question. 20 Q. Do you know whether this is a And I think Mr. Aylstock is right: 21 representative specimen? 21 That that's far afield from his testimony that this 22 MR. CURTIS: Objection. 22 particular Figure 4 depicts deformed mesh in this 23 Representative of what? 24 /// particular patient.

11 (Pages 38 to 41)

Page 44 Page 42 1 BY MR. SNOWDEN: 1 particular section, it wasn't in continuity with the 2 Q. Of the whole -- of Ms. Carter's specimen. 2 epithelium. 3 Let me ask it again. 3 Q. Do you recall there being five portions of 4 Do you know whether this is a 4 tissue on the slide you reviewed in this case? 5 representative specimen of the whole of Ms. Carter's 5 6 excised mesh? 6 Q. Is there any reason you didn't take 7 7 A. I would -- well, it's my opinion, just photographs of the other four? 8 8 based on how your body reacts to foreign material, A. They didn't have mesh, and the report was 9 that this would be representative of what's not 9 on the reaction to the mesh. sampled that's in her body. 10 10 Q. Is the -- did you remark at all about the Q. So the inflammation we see here in the 11 11 tissue in the other four pieces in your report? 12 fibrosis, we see here you expect that to be 12 A. Yes. 13 equivalent or similar throughout the rest of the 13 Q. Where is that? 14 14 A. It's under the microscopic findings. specimen. 15 A. I would say that it would be similar, 15 Q. All right. So what's your opinion 16 although changes obviously occur if it's -- because 16 regarding what you saw in those other four pieces? 17 in this area, we don't actually have it eroding 17 A. Well, as I say, I say, "The histologic 18 through the mucosa. section show numerous fragments of tissue, some of 18 19 So when it's eroding through the which are lined by reactive and acanthotic squamous 19 20 mucosa, I would imagine there would be more acute 20 mucosa with underlying stromal edema, and others inflammation or hemorrhage or edema, depending on if 21 that show fibromuscular and fibroneural tissue." 21 22 it's located near -- you know, if there's mesh near And then I go on to say, "In one 22 the -- some of her mesh has migrated. It's near the 23 fragment ..." and I describe the mesh. 24 urethra, it may be involving smooth muscle or it 24 Q. Okay. Was there anything significant about Page 43 Page 45 could be involving skeletal muscle, which could those other four pieces? 2 A. I didn't think that there was anything 2 cause, again, a slightly different response. 3 But, generally, I would say that it 3 other than what I described that showed significant 4 would be similar, the basis of the inflammatory pathologic change other than the stromal edema 5 5 response. that's underneath the mucosa. 6 6 Q. You brought up a good point. Q. Figure 4: Do we see any nerves in this 7 You didn't see the erosion site in this 7 clear micrograph? 8 8 case, did you? A. It's hard to tell if there are any nerves 9 at this magnification. 9 A. Correct. This was the only slide I have. 10 Q. So you didn't see any mucosa. 10 If they are, they would be small, and A. I don't remember if there was mucosa on 11 I didn't think that they were within that fibrosis 11 this. It wasn't -- let me look. I thought that 12 of the -- between the mesh. there was, it just wasn't at the mesh. 13 Q. Is it fair to say you didn't find any 13 14 Yeah. There's squamous mucosa. 14 nerves that you would consider were entrapped in the 15 Q. And did you -- did you see mesh near the 15 scar tissue? A. Yes. I agree with that. squamous mucosa in this? 16 16 17 17 A. Well, I mean, it depends on how you define Q. Okay. Is it fair to say you didn't find 18 "near." 18 any deformed nerves in this case? 19 19 Q. How do you define it? A. Yes. And I didn't have an S100, which A. Well, it's within a few millimeters of the limited my ability to find any. But based on HNE 20 20 mucosa. That's certainly closer than if it was 21 alone, I did not see any deformed nerves in this 21 5 centimeters away. You would say that that was 22 case. 23 23 relatively near compared to something farther. Q. So fair to say, then, there are no

12 (Pages 42 to 45)

24 traumatic neuromas in this specimen that you

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So -- but it wasn't -- in this

Paul J. Michaels, M.D. Page 46 Page 48 reviewed? dyspareunia, pain to palpation. And then 1 1 2 A. I didn't notice any traumatic neuromas in 2 extrapolating based on, as we talked about, knowing 3 the specimen. 3 that these findings would be representative of other 4 4 Q. Would that have jumped out at you? A areas of her mesh that were not removed. 5 traumatic neuroma. 5 Urethral fistula formation, recurrent 6 A. It depends. It should. 6 urinary tract infections, and a recurrent stress 7 7 Q. What do we see in Figure 5? urinary incontinence. Knowing that this was in an 8 A. Well, again, we see prominent hypocellular 8 area away from her bladder, but knowing that the 9 and hyalinized fibrosis that's extending between 9 same mesh substance was in other areas, I would say these mesh filaments that I have with arrows. And 10 you could extrapolate from that, which we do as 10 pathologists all the time when we only see a small 11 at the arrows you can also see a chronic 11 12 bit of tissue but have to make an evaluation based 12 inflammatory and foreign body response. Q. We also see blood vessels in Figure 5. Is 13 on a larger specimen. 13 14 BY MR. SNOWDEN: 14 that right? 15 Q. In answering my question, I notice you 15 A. There are tiny compressed blood vessels. Q. So you'd agree this tissue is vascularized. 16 16 reviewed a portion of your report. 17 A. Well, there are vessels in it, but they are 17 Were you looking for the clinical compressed and I don't see red blood cells within 18 symptoms that Ms. Carter experienced? Was that part 18 of what you had reviewed? 19 19 them. It's certainly not necrotic. It's not -- it 20 A. No. I was reviewing what I reported and 20 doesn't look like there's no vascular supply getting 21 21 the actual time of when this mesh was taken out, and to it. 22 22 Q. Are those red blood cells in the what I had summarized. 23 granulomatous tissue described in Figure 2, and are 23 Because there's a lot of information actually pictured in Figure 5? That's the left 24 in these cases, and before I give you a thoughtful Page 47

portion of the picture.

A. Yeah. At the edge.

Q. What are the tiny -- other than the chronic inflammation, what are the tiny purple dots in Figure 5?

6 A. They're a variety of cells.

7 Q. Did you look at these to determine what 8 type of cells these were?

9 A. Well, they're fibroblasts, and they're 10 endothelial cells, and they're perimyocytes associated with the vessels. There are probably 11 some mast cells that you often see in stromal 12

13 tissue.

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14 Q. Anything else?

A. Nothing striking that jumped out at me.

16 Q. We've gone through five of your figures and you've described your findings in them. Can you 17 18 tell us what impact this is having on Ms. Carter?

19 MR. CURTIS: Object to the form of the 20 question.

21 (Document review.)

22 A. So I would say that based on the features that I identified histologically that they would be a morphologic explanation for her symptoms

answer that I want to be accurate and precise, I

wanted to review to make sure that what I'm saying 3 are her symptoms or her -- what impact this tissue

4 had is accurate.

5 Q. Had you looked solely at the tissue without 6 any clinical history in this case, could you have 7 told us those clinical symptoms?

8 MR. CURTIS: Object to the form of the 9 auestion.

10 A. I didn't do that. That's not what I was 11 asked to do.

12 BY MR. SNOWDEN:

13 O. Okay.

A. So I can't really postulate what I could

15 have done without that scenario. I wasn't in that 16 scenario.

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17 Q. But are you able to look at any of these 18 figures in your report and tell me what impact this tissue reaction is having, was having, on 19

20 Ms. Carter's pain?

21 MR. CURTIS: Object to the form of the 22 question.

23 A. Well, I don't operate in a vacuum, so I can't just look at one picture and tell you

13 (Pages 46 to 49)

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Page 50 everything about the patient.

I, and other pathologists and other physicians, have to take everything into account and put them together and rule out other etiologies of pain. And there are tons of etiologies of pain you can identify microscopically, and I didn't find any of them in this material.

So I can't just look at one picture in a case like this and dictate what kind of symptoms or signs she was showing.

#### BY MR. SNOWDEN:

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Q. How about all the pictures? Could you look 12 at all the pictures and say that? 13

MR. CURTIS: Object to the form of the 14 15 question.

#### BY MR. SNOWDEN:

Q. Let me reask the question.

If you look at all the pictures together, would you be able to do that?

MR. CURTIS: Object to the form of the question.

22 A. Again, I told you regarding any of these 23 I'm not operating in a vacuum. I wasn't just asked to look at the histology and write a report about

Page 52

inflammation, it's going to move within the tissue, 1 2 and, depending on the location, can lead to urinary 3 dysfunction.

Q. Did this mesh that we're looking at in these five figures lead to urinary dysfunction?

A. Well, this particular mesh was -- again, it was taken from posteriorly, so it wasn't in that area.

So as we've already -- as I've already mentioned, I think you can take -- well, it's my opinion that you can take these inflammatory processes that are occurring in a mesh that is uniform throughout its actual product.

It's not as if when you have a mesh product they coat part of it in one polymer and another part in something else and then they add other coating to another part. It's uniform.

So the tissue reaction you see in a small amount would correlate and you can extrapolate to other parts of the tissue, assuming that it's in other parts of the body, which it is.

22 It's not just in this posterior 23 vaginal wall, it's in other -- this is just -- this 24 isn't representative of how much tissue -- how much

Page 51

what my findings were. 1

> I was asked to look at the histology in conjunction with the medical records and issue a report basically saying what I felt if I felt like these correlated, which I do.

And part of that was evaluating the tissue and making sure there weren't other findings. And there are several that can be found in any given case that could have basically said that these other finding, in addition to the mesh, this other finding actually could have equally have produced pain, and I didn't see any evidence of that in this case.

#### BY MR. SNOWDEN:

14 Q. How did the reaction to the mesh -- how does it correlate with the clinical symptoms in this 15 16

17 A. Well, the inflammation and the scarring 18 would lead to basically deformation and an inflammatory reaction associated with the actual 19 filaments that are present. And the contracture, based on the fibrosis, would lead to an anatomic, 21 basically, malfunction, if you will, of the general 22 area and could lead to pain. Obviously, the

extrusion, because when it's contracting and there's

mesh she has in her body.

2 Q. Did you review a specimen taken from 3 Ms. Carter's anterior vaginal wall?

A. No. I think we've already gone over that.

This is the one specimen that I have where there are five fragments of the tissue that are on the slide, and it was taken, reportedly, from the posterior vaginal wall.

9 Q. Which device are we looking at in these 10 figures? 11

A. The Prolift.

12 Q. What aspect of the Prolift device led to 13 the changes -- the tissue changes we're looking at 14 in these figures? 15

MR. CURTIS: Object to the form of the 16 question.

17 A. I don't know what you mean.

18 BY MR. SNOWDEN:

19 Q. What about the Prolift led to these tissue 20 changes, if you know?

21 A. I don't know what you're talking about. I 22 don't understand that question.

23 Q. How did the Prolift cause these tissue 24 changes which you're correlating with Ms. Carter's

14 (Pages 50 to 53)

Page 53

Page 56 Page 54 symptomatology in this case? 1 fibrosis. So when I'm talking pathologically about 1 2 A. Because it's a synthetic foreign body. 2 the contraction, I'm talking about what's causing it 3 I don't know what you're getting at. 3 which is the fibrosis; and no, I didn't quantify any 4 4 I don't understand. element of the contraction or fibrosis. 5 5 Q. I'm asking -- I'm just asking for your Q. Is there anything you could have done to 6 opinion on what aspect of the Prolift device led to 6 measure or quantify the contraction in this case? 7 7 the tissue changes you're correlating with A. Not that I would have done that I'm aware 8 Ms. Carter's symptomatology? 8 of. 9 MR. CURTIS: Object to the form of the 9 Q. Do you have an opinion in this case that Ms. Carter's mesh migrated? 10 question. 10 11 A. The polypropylene mesh and its 11 A. Yes. 12 characteristics. 12 Q. Okay. And what's that opinion? 13 BY MR. SNOWDEN: 13 A. That it did. 14 Q. Okay. Which characteristics led to the 14 Q. Okay. Where did it migrate from? A. I can't give you exact anatomic locations. 15 tissue changes we see here? 15 16 A. I guess I don't understand the question. 16 But the fact that it was eroded through the mucosa, 17 Q. Do you have an opinion as to the specific 17 by definition, is a migration. elements of the Prolift device that led to the 18 18 So I don't -- I can't tell you that it 19 tissue changes we see in Ms. Carter's case? 19 took a 135-degree turn and went anterior, 20 posterior -- anterolateral. 20 MR. CURTIS: Object to the form of the 21 21 But it migrated from its normal question. 22 location to coming out of the body. That's, by 22 THE WITNESS: Can you repeat the last 23 question? 23 definition, migration. 24 24 Q. In your opinion -- strike that. THE REPORTER: Yes. Page 55 Page 57 1 (The record was read as requested: 1 Figure 5 you have in the legend 2 "Do you have an opinion as to the 2 "Prominent hypocellular and hyalinized fibrosis." 3 specific elements of the Prolift 3 Do you see that? 4 device that led to the tissue changes 4 A. Yes. 5 5 we see in Ms. Carter's case?") Q. What do you mean when you say "hyalinized"? 6 A. It means it's -- just for a layman's term, 6 A. So, I guess, getting back -- I'm assuming 7 7 it's very pink and hypocellular. It's kind of -this is a general question with regards to Prolift 8 8 in general. when it's hyalinized, it has a glassy appearance. 9 9 Microscopically, it tends to be So, as we covered earlier, the heavy 10 weight, the pore size, its location I would say in 10 associated with these clefts, which you can see, that anatomic region. All those together would which are these almost white tiger stripes that 11 11 12 correlate with the findings that we're seeing. 12 traverse horizontally. 13 That's hyalinization. 13 BY MR. SNOWDEN: 14 Q. Did you quantify the degree of contraction 14 Q. Is the presence of hyalinized fibrosis in Ms. Carter's case? 15 significant to your opinion? 15 A. It's just evidence of dense fibrosis which 16 16 A. No. We don't quantify fibrosis in you see in the setting of scars. 17 non-research settings in this location in the body. 17 18 Q. And I just want to make sure we're talking 18 Q. Are you offering an opinion in this case that Ms. Carter's mesh degraded in vivo? 19 about the same thing. 19 20 20 I'm asking about the contraction of the mesh that I believe you've said you're opining 21 Q. And what's the basis for that opinion? 21 occurred in this case. Did you quantify the degree 22 A. My microscopic evaluation using 22 23 polarization microscopy. 23 of that contraction? Not the degree of the fibrosis. 24 A. Well, the contraction is secondary to the 24 Q. Where did you get the idea to do that?

15 (Pages 54 to 57)

Page 58 1 A. From the literature and from Ethicon's own cracking of that outer layer. 2 scientists who did the same thing. 2 Q. Which literature? 3 3 4 4 A. Well, I don't know the exact names of the A. Um-hmm.

studies. I know just a couple days ago I was 6 rereviewing this and was, again, seeing the reports 7 from Ethicon scientists that showed the same 8 degradation.

9 And so when I first got involved, I 10 was sort of pointed to that material because 11 obviously, as a layperson in the medical community, I didn't have access to Ethicon's internal 12 13 documents.

14 So those were provided to me, and then 15 I did my own literature search and had other article -- peer-reviewed articles that I could 16 17 review, like Dr. Iakovlev's article, and saw the findings, read about the findings. Read about the 18 19 scanning electron microscopy, its correlation. 20 The prior medical literature,

21 postulating about biofilm and that it's a protein polymer and not really a foreign synthetic material. 22

23 And so after reading all of that and seeing them talking about polarization light microscopy, that's

Q. And I think what you're referring to now are cracks with SEM photos. Is that right?

Page 60

Page 61

5 Q. Okay. And I want to focus specifically on what we're -- the specimen you reviewed -- well, let 7 me start over.

8 Did you do any scanning electron 9 microscopy on this specimen?

A. No.

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11 Q. Did you do any transmission electron microscopy in this specimen? 12

A. No.

14 Q. Did you do any analytical chemistry tests 15 on this specimen?

16 A. No.

17 Q. Okay. Your review of this specimen was limited to light and polarized light microscopy. 18

Would you agree? 19

A. To the specimen, yes.

21 Q. And so the specimen we're talking about 2.2 right now --

23 MR. SNOWDEN: I don't want to get into

general opinions so that I draw a bunch of

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why I polarized these cases.

Q. What about the specimen in this case supports your opinion that the mesh degraded in vivo?

A. The outer polypropylene bark, or layer -whichever you prefer to use -- is detached from the core, and it's also detached from the surrounding tissue and it's broken into numerous pieces.

9 Q. And is that what you have shown in 10 Figure 6? 11

A. Yes.

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Q. How did you -- well, let me start over.

13 Did you rule out artifacts of microtomy 14 when determining that Figure 6 was degraded 15 polypropylene?

A. Yes. It's my opinion from reviewing the 16 literature that these findings are not from any sort 17 18 of microtome or processing. 19

Q. And why is that?

20 A. From what I've read, that even without

21 those -- in the pictures that I've seen, even

without those processing features that you would 22

still see the same findings without formalin

fixation or cutting or anything. You still see

objections from you guys. 1

MR. CURTIS: Just ask your question.

MR. AYLSTOCK: Did I look like I was going to object? I'm sitting here minding my own business.

BY MR. SNOWDEN:

7 Q. From your review of the polarized light 8 microscopy and light microscopy in this case, what 9 is it that led you -- how did you rule out that this

10 bark was not just an artifact of processing or

11 microtomy? 12

MR. CURTIS: Object to the form of the 13 question.

14 A. Because it doesn't have that appearance.

15 After years of looking at processing 16 artifacts, it doesn't have that appearance. You don't see multiple little -- you wouldn't see this 17

18 kind of architecture based on a microtome blade. It

19 just makes -- it doesn't make any pathologic sense 20 to me.

21 BY MR. SNOWDEN:

22 Q. Did you see any -- well, hold on one

23 second. Sorry. 24

(Pause in proceedings.)

16 (Pages 58 to 61)

Page 62 Page 64 1 BY MR. SNOWDEN: non-degraded polypropylene? 1 2 Q. Other than Dr. Iakovlev's article and the 2 MR. CURTIS: I object to the form of 3 Ethicon study that you referenced earlier, do you 3 the question. recall any other articles you're using for the basis 4 A. Because it's morphologically similar to 4 5 of your degradation opinion? 5 what's been described with respect to degraded 6 And I'm specifically asking about with 6 polypropylene. And that's -- as a pathologist, 7 7 the use of light microscopy. that's the basis of my entire career is, you use A. I can't recall. 8 literature and your own training and images of what 8 9 Q. Do you recall in the article by Iakovley, 9 is described as X, and then you see it yourself and 10 and others, that he -- one of the ways he asserts you say, Based on my opinion and based on my 10 knowledge of what is out there in the literature, 11 you can differentiate between non-degraded 11 polypropylene and degraded polypropylene is the what has been published, this is analogous to what 12 12 uptake of histologic stain? 13 is being described, and you come to your own 13 14 14 MR. CURTIS: I don't know why this is conclusions. 15 15 not general. I mean, you're not asking him about So when I reviewed this particular his bases for the judgment he made in this case, 16 case and looked at what we're seeing on Figure 6, my 16 17 you're talking about these --17 opinion is that that is degraded -- that's evidence 18 of degraded polypropylene bark and not a processing MR. SNOWDEN: I absolutely am. 18 19 19 or sectioning artifact. MR. CURTIS: You're talking about 20 these articles and all this other stuff that was 20 BY MR. SNOWDEN: specifically covered. This same topic, this same 21 Q. And what morphologic features are you using 21 author, this morning in the general. 22 to come to that conclusion? 22 BY MR. SNOWDEN: 23 23 A. Well, as I said earlier, the fact that it's 24 Q. You can answer the question. 24 separated from the core. Page 63 Page 65 1 MR. CURTIS: I object to the question. 1 It's in multiple fragments. 2 2 A. Can you repeat the question? It's also separated from the 3 MR. SNOWDEN: Can you repeat the 3 surrounding tissue. 4 question, please. 4 You can't see that blue dye, because 5 5 (The record was read as requested: this is a polarized picture, so you can't see the "Do you recall in the article by 6 6 actual blue dye. 7 Iakovlev and others that he -- one of 7 But just based on those features, 8 the ways he asserts you can 8 that's -- and correlating with the literature, 9 9 differentiate between non-degraded that's how I came to that conclusion. 10 polypropylene and degraded 10 Q. Anything else? Any other morphologic polypropylene is the uptake of 11 11 similarities? 12 histologic stain?") 12 A. I think I described the main ones. MR. CURTIS: Let's take a break, if A. I would have to see the article. 13 13 14 BY MR. SNOWDEN: 14 this a convenient spot. 15 Q. You don't recall that? 15 MR. SNOWDEN: I'd like to get through 16 A. I recall there being a mention about the 16 this line of questioning first, please. 17 stain, but I don't remember that it was specifically 17 THE WITNESS: I actually need to use 18 in regards to whether it's degraded or non-degraded. 18 the restroom. And before I answer any question about the article, 19 19 MR. SNOWDEN: Okay. 20 20 I'd like to see the article. MR. THOMAS: Let's take a break. 21 21 Q. How do you determine, when you're looking MR. SNOWDEN: Over my objection. 22 under the microscope and coming to your opinions in 22 (Recess from 1:20 p.m. to 1:26 p.m.) 23 a mesh case, that the fragments you see depicted in BY MR. SNOWDEN: 24 Figure 6 are degraded polypropylene rather than 24 Q. Dr. Michaels, what, if any, clinical

17 (Pages 62 to 65)

Page 66 Page 68 significance do you attribute to the degradation of 1 Q. Other than --Ms. Carter's specimen? 2 2 A. I was going to say, not physically, just 3 A. Well, the degradation of the polypropylene 3 her tissue. leads to increased inflammation which would then 4 Q. Other than the one tissue slide you lead to increased fibrosis, which would correlate 5 reviewed in this case, have you ever examined 6 with her symptoms that I described in my report --6 Ms. Carter? 7 7 and signs in my report. A. No. 8 8 Q. That any -- and all symptoms attributed to Q. Have you ever spoken with Ms. Carter? 9 the degradation layer? 9 A. No. 10 A. Well, that's one aspect of the foreign body 10 Q. Have you -- were you present during any of response. It increases the response and the the surgical procedures Ms. Carter had? 11 inflammation which would then increase the fibrosis, 12 12 13 so that's one element of it. 13 Q. Did you have an opportunity to view the Q. Did you do a measurement of the degradation 14 mesh in vivo? 14 15 layer in this case? 15 A. No. 16 A. No. 16 Q. Did you have an opportunity -- strike that. Have you read -- well, which 17 Q. Did you do any type of nerve density 17 analysis in the specimen? 18 depositions, if any, have you read regarding 18 A. Well, I described earlier how there weren't 19 19 Ms. Carter's case? 20 any nerves that were entrapped. 20 A. Well, that's hard to answer, because within 21 So -- and I would only take into 21 her case I have general opinions in this report that account what nerves were in the area of the mesh. I had reviewed multiple depositions from Ethicon 22 22 So I didn't do any -- and even regardless, I would 23 scientists and -- and then I've also, since this feel that that's something that would be more likely report, reviewed her -- her deposition testimony. Page 67 Page 69 1 in the setting of a research study and similar to But I don't recall reviewing any, 2 grading of inflammation in fibrosis that we've like, treating physician testimony in this case or 3 talked about. So I personally don't do that. 3 any other expert testimony in this case. Q. Did you consult with a neuropathologist in 4 Q. And that's really what I'm after. 5 5 this case? I'm after the case-specific materials 6 6 A. No. relating to Ms. Carter and not depositions of 7 7 Ethicon's employees or anything sort of in the Q. Did you consult with any other pathologists 8 regarding Ms. Carter's specimen? 8 general portion of your report. 9 9 MR. CURTIS: That was all covered this If you turn actually to Exhibit --10 morning, his consultation with neuropathologists and 10 well, it's toward the end of your report. You have a other pathologists and even other experts. 11 list, "Case-Specific Materials Reviewed." It's 11 12 Exhibit C -- let me make a better record of that. 12 MR. SNOWDEN: Regarding Ms. Carter or 13 13 not? Exhibit D to your report. Is this your 14 14 reliance list? MR. CURTIS: Regarding all six cases. 15 A. No, I did not. 15 A. Yes. I provided the portion that's with my 16 BY MR. SNOWDEN: font, Garamond or ... 16 Q. And so beginning on page 5, was that 17 Q. Have you spoken with any of the other --17 18 well, strike that. 18 provided by counsel for the plaintiff? 19 Have you spoken with anyone else other 19 A. Yes. 20 than counsel for the plaintiffs regarding 20 Q. Do you recall reviewing the deposition of Ms. Carter's case? 21 Dr. Weiss? 21 22 22 A. No. A. I don't believe so. 23 Q. Did you review the deposition of 23 Q. Have you ever examined Ms. Carter? 24 David Carter? 24

18 (Pages 66 to 69)

Page 70 Page 72 2.5. 1 A. I don't recall. I don't think so. 1 2 Q. Did you ask for all of the medical records 2 So if someone's saying, Yeah, it 3 in this case? 3 didn't look deformed, you'd have to ask more 4 4 specific questions. A. Yes. 5 Q. Do you know if you've received all of them? 5 Well, was it exactly the way it was 6 A. I mean, I didn't receive her, like, 6 when it was put in, or do you mean it wasn't 7 7 completely twisted around? pediatric records. 8 8 Is that what you define "deformed?" I have no way of knowing if I received 9 all of someone's medical records. I have no way of 9 So it's based on a particular clinician or any physician's definition of what term 10 knowing that. 10 11 Q. Was there anything you requested 11 they're using. But I would want to see what was specifically to Ms. Carter that you were not exactly described about it. 12 12 provided? 13 Because that would be -- I would 13 14 think, just based on the limited amount of tissue I 14 A. I don't recall requesting anything that I saw, I would be surprised that it looked normal. 15 wasn't provided in Ms. Carter's case. 15 16 Q. Are there any other depositions relating to 16 BY MR. SNOWDEN: Ms. Carter's care that you've reviewed that are not 17 Q. Sitting here today, you don't know one way 17 on this list? or the other how the explanting physician testified. 18 18 A. I don't know the specific words because I A. Not that I recall. 19 19 20 Q. What effect, if any, on your opinion that 20 already told you that I didn't review his you stated earlier that the mesh deformed would the 21 deposition, so no. 21 fact that the explanting physician found no roping, 22 And I don't remember there being a 22 23 curling, or deformation of the mesh? 23 mention in the operative report that specifically 24 MR. CURTIS: Object to the form of the 24 said that it looked normal or that it wasn't Page 71 Page 73 1 question. 1 deformed. So I don't recall that. 2 2 A. I would have to see that -- where that was Q. Did the operative report mention that the 3 described and see what words were used. I can't --3 mesh was deformed? I mean, I would like to see where that's described. 4 A. I don't recall. I've looked at a lot of 5 5 BY MR. SNOWDEN: operative reports. I'd have to rereview it. Q. Is that something that could be important 6 (Exhibit 2 marked.) 6 7 for your opinion if the clinician who saw the mesh 7 BY MR. SNOWDEN: 8 8 in vivo said it was not deformed? Q. I'm handing you what's been marked 9 MR. CURTIS: Object to the form of the 9 Exhibit 2. 10 10 Dr. Michaels, have you reviewed this question. 11 record previously? 11 A. Well, it's somewhat subjective. I've certainly had many surgeons remove things and say, A. Yes. 12 12 "This tumor was 4 centimeters big." 13 Q. And what is this record? 13 14 And then I get it and cut it and it's 14 A. It is the pathology report from the mesh. 2.5 centimeters. Q. And is this the pathology report from the 15 16 hospital where the mesh was removed and then you 16 So in that situation, who's right? I subsequently received a portion of that? 17 am. 17 18 I'm the one that cut it; I'm the one 18 A. Yes. that measured it. If someone's saying -- the 19 Q. Okay. Does this hospital -- well, strike 19 20 20 that. surgeon is saying, Well, this is -- well, okay, 21 21 that's --Let's take a look down at the gross 22 22 description. It says, "Received in formalin labeled Okay, that's fine. It was 'Carter, Tamara L, DOB 9/7/1959,' and 'mesh' are four 23 2.5 centimeters. I felt like it was 4. Okay. But I measured it and it was irregular, ragged fragments of white and blue 24

19 (Pages 70 to 73)

Page 76 Page 74 synthetic mesh material, with embedded tan-pink about deformation? prominently congested soft tissue, that vary from 2 A. I don't see anything in the bolded 0.7-1.5 cm in greatest dimension, and are 2.3 by 2.0 3 diagnosis that says anything about deformation. 4 by 0.8 cm in aggregate." Q. Anything in the bolded diagnosis or gross 5 Do you see that? 5 description about roping or curling? 6 A. Yes. 6 A. Well, again in the gross description -- you 7 7 know, you're trying to ask if they use -- if there Q. It also says "representative sections of soft tissue are submitted as A1." 8 is a very specific finding when they're using 8 9 Do you see that? 9 nonspecific terms. 10 10 So "irregular and ragged" could be A. Yes. 11 Q. So the specimen that you reviewed in this 11 describing something that is roped or curled. Just case was a portion of the whole specimen that was because they're not using the words "roped or 12 12 sent to pathology. Is that right? curled," doesn't mean that they weren't. 13 13 A. Yes. 14 And they are, again, not saying that 14 15 Q. And if we look at the diagnosis that's a 15 these are regular, they're not saying that they're couple of lines above the gross, do you see anywhere 16 smooth. They're saying that these are irregular and 16 where the pathologist notes deformation of the mesh? 17 ragged, so I think that actually supports the fact 17 A. Well, deformation wouldn't be something that this is not normal mesh. 18 18 that would be listed in the diagnosis. You wouldn't 19 19 Q. Do you see any mention on this pathology put that in the diagnosis. 20 report of mesh degradation? 20 21 If anything, it would be in the gross 21 A. I do not see that they evaluated for mesh 22 description, which -- in which they're described as 22 degradation in this report. irregular and ragged fragments of white and blue 23 23 Q. Did they use a light microscope? 24 A. They did use a light microscope, but synthetic mesh. Page 77 Page 75 1 So actually, in fact, he is describing there's no mention of polarization microscopy. that these are irregular and ragged, which I would 2 2 Q. Do you need a polarized lens to assess 3 say -- a synonym of which could be "deformed," 3 degradation in this case? depending on how you -- depending on how you use the 4 A. You don't need a polarized lens to assess term "irregular and ragged." 5 5 degradation, but they also did not do a microscopic That's certainly not normal, 6 description. So there's no -- we have no idea of 6 7 flattened, you know, mesh. It's clearly describing 7 exactly what they saw, it was just incorporated into 8 something that is deformed. 8 the final diagnosis. 9 Q. And you saw representative sections of 9 Q. Okay. Do you know Dr. Jonathan Strauss? 10 those four pieces on the -- on your slide. Right? 10 A. I know of him. A. Of the pieces of tissue? 11 11 Q. Do you know where he went to medical 12 O. Um-hmm. 12 school? A. Yes. 13 13 14 Q. And those pieces of tissue weren't just 14 Q. Do you know what his research interests perfect circles or squares, they were sort of ragged are? 15 fragments of tissue. 16 16 A. No. 17 A. That's one dimension. 17 Q. Do you know if he's avid in the field of 18 You know, this is different than the 18 degradation of polypropylene? 19 gross evaluation. 19 A. No. 20 Q. All right. Do you see the word 20 Q. Do you know his day-to-day methods of 21 "deformation" on this? 21 evaluating mesh specimen? 22 A. I don't specifically see the word 22 A. No. 23 "deformation" on this. 23 Q. Is there anything about -- strike that.

20 (Pages 74 to 77)

Does this pathology report correlate

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Q. Okay. Do you see anything in the diagnosis

Page 78 Page 80 post-op of pain, is there? these findings to any of Ms. Carter's symptoms? 2 2 A. I don't understand what that question A. I don't see anything about the word "pain" 3 3 means. 4 4 Q. And there's no mention of dyspareunia in Q. Looking at this pathology report, does this 5 pathologist, Dr. Strauss, correlate his findings to 5 the pre-op or post-op. 6 Ms. Carter's symptoms? 6 A. Not in the pre-op or post-op of the 7 7 A. I don't see any comment in this pathology clinical information on the pathology report, that's 8 report attempting to correlate these findings with 8 correct. 9 Ms. Carter's symptoms. 9 Q. What's your understanding of why the mesh Q. And -- because you normally wouldn't see specimen you reviewed was removed from Ms. Carter? 10 10 that in a pathology report from a hospital 11 A. Well, it looks like Dr. Weiss had noted a 11 specifically. Is that fair? 12 firm foreign body suburethrally, and then underwent 12 13 A. Well, it depends. It depends on what kind 13 an exploration for that suburethral mesh with a of specimen you're dealing with, and if you're asked repair of a urethral injury, and then removed a 14 14 15 perirectal foreign body. It was based on the 15 to do that. 16 And in some specimens, we are asked to 16 erosion. 17 do that. We are asked to correlate the findings or 17 Q. Okay. Any indication to you that the mesh to mention if the findings do not correlate. 18 was removed due to pain? 18 And so in this particular example, he 19 A. My recollection from her deposition was 19 20 didn't say anything. So there's no mention that he 20 that she was experiencing pain at this location. was asked to or that he would feel comfortable to, 21 Q. And from the medical records -- before I 21 or if he knew the literature with regards to mesh 22 ask that question. 22 23 and complications, so no. It's just a simple 23 What location are you talking about? pathology report. 24 A. The posterior vaginal wall and also, I Page 79 Page 81 1 Q. For all you know, he could have spent the think, suburethrally. Even though we don't have 2 2 last two months doing 161 to 201 hours reviewing that specimen. 3 literature. Right? 3 Q. Where did the specimen go that was removed 4 MR. CURTIS: Object to the form of the 4 suburethrally, if any? 5 question. This is argumentative. 5 A. I don't know what was done with it, or if A. It's pretty petty and nasty, frankly. 6 it was -- what was done. 6 7 And I don't know anything about 7 Q. You reviewed the record from Dr. Strauss and what he did prior to issuing this 8 8 September 27th, 2012? pathology report on Ms. Carter in 2012. 9 A. I don't know what record you're talking 9 10 10 BY MR. SNOWDEN: about. 11 Q. All right. Looking at the diagnosis. 11 The pathology record? Is the diagnosis found here consistent 12 Q. I'm sorry. The operative note from that 12 with your diagnosis? 13 13 date. 14 A. I would say so. 14 A. Yeah. I'd have to look at it again. I 15 Q. Anything different in this diagnosis from 15 don't recall as I'm sitting here what it said. 16 Q. Before coming to your opinion, are you 16 yours? A. Well, obviously, I've expanded on mine. offering any opinions in this case regarding 17 17 18 But I would say superficially, they're -- we found 18 Ms. Carter's anterior vaginal wall?

21 (Pages 78 to 81)

A. Well, as we've already discussed, I am extrapolating the findings that I am seeing in her

posterior vaginal wall from the specimen that I

received. And extrapolating those findings and correlating them with her symptomatology that would

have been affected by pathology of the anterior

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similar things with regards to what he reported.

top, it mentions pre-op and post-op.

Do you see that?

A. Um-hmm.

Q. If we go to the clinical information at the

Q. And there is no indication on the pre-op or

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Page 84 Page 82 mesh removed on September 27th, so her symptoms -vaginal wall, given that the mesh has similar biologic properties and there's still mesh that's 2 2 let me review this. 3 3 within her body. (Document review.) 4 4 Q. So just so I understand. A. From my recollection, she had persistent 5 5 Any opinion you have on the anterior symptoms even after the small amount of mesh was 6 vaginal wall is not -- it's based on an extrapolation 6 removed. 7 7 from the specimen you reviewed from the posterior So I would say based on my findings 8 8 vaginal wall. Do I have that right? from that particular day, knowing that there is 9 A. Right. Which is consistent with what we do 9 still a significant amount of mesh material in that 10 on a day-to-day basis as pathologists where we have 10 anatomic location, I would say that I would feel 11 comfortable correlating her symptoms based on my 11 a small amount of tissue that's felt to be representative of a larger process. And we have 12 examination of the mesh from this case. 12 opinions and form opinions and make extrapolations 13 BY MR. SNOWDEN: 13 based on that material. That's correct. 14 Q. And that opinion about symptoms that 14 15 postdated the September 27th, 2012, surgery that's 15 Q. Did the treating pathologist in this case 16 extrapolate about the anterior vaginal wall in 16 not based on any new mesh specimen you reviewed? 17 17 rendering this pathologic diagnosis --A. No. I would just say that it would be -depending on what I was asked, if she developed some 18 MR. CURTIS: Object --18 19 19 sort of new complication or a different quality of a Go ahead. 20 BY MR. SNOWDEN: 20 symptom, then that would obviously -- you know, I 21 Q. -- about the explanted posterior mesh? 21 wouldn't be able to be as confident about MR. CURTIS: Object to the form of the correlating that with her current specimen that I 22 23 question. 23 could with the current one with the symptoms she was 24 having prior to the surgery on September 27th, 2012. 24 A. Can you repeat that? Page 83 Page 85 1 1 MR. SNOWDEN: Can you please repeat Q. When you were evaluating the post 2 2 that? September 2012 symptoms, did you -- did you consider 3 3 deposition testimony of Dr. -- and I'm going to (The record was read as requested: 4 4 "Did the treating pathologist in this butcher this name -- Tenggardjaja? 5 case extrapolate about the anterior 5 MR. SNOWDEN: I'll give you the 6 vaginal wall in rendering this 6 spelling afterwards. 7 pathologic diagnosis?") 7 THE REPORTER: Thank you. 8 8 A. I don't see that he made any clinical A. Well, given that I've already said that I 9 comments on this pathology report in general. 9 didn't review any other deposition transcripts, I 10 MR. CURTIS: How much more time do you 10 would say, no. 11 BY MR. SNOWDEN: 11 show? 12 12 Q. Okay. On page 2 of your report under MR. SNOWDEN: 16 minutes. 13 13 number 7, you have a statement that begins THE REPORTER: Would you like me to 14 "Ms. Carter's reported signs and symptoms of 14 check? 15 MR. SNOWDEN: Sure. 15 exquisite pain to palpation, dyspareunia ..." and 16 MR. CURTIS: Yes. 16 then it goes on. 17 17 THE REPORTER: I have 1 hour and 43 Do you see that? 18 minutes on the record. 18 19 19 BY MR. SNOWDEN: Q. Does it matter to any of your opinions that 20 Q. Doctor, will you be offering any opinions Dr. Tenggardjaja testified that he felt Ms. Carter's 20 at trial regarding any symptoms experienced by 21 pain was exaggerated? 21 Ms. Carter after the mesh was removed on 22 MR. CURTIS: Object to the form of the 22 23 23 September 27th, 2012? question. 24 A. Well, there was only a small portion of the 24 A. No.

22 (Pages 82 to 85)

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Page 86

BY MR. SNOWDEN:

2 Q. Why not?

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A. Because pain is subjective. And, you know, if someone under oath, or regardless, is saying that they have significant pain and there's a reason for that pain, which pathologically my opinion is that there would be a reason for that pain, whether another physician deems it to be exaggerating or not doesn't completely disqualify it.

Q. Earlier in the deposition you mentioned that there were -- I think you said tons of etiology 11 of pain. Do you recall that?

A. Was that in this deposition?

14 O. I believe so.

Anyway, are there multiple etiologies 15 of pain? 16

A. Biologically, yes; and pathologically.

Q. And you would agree psychiatrically?

A. Potentially. 19

20 Q. Did you -- did you review -- well, let me

21 start over.

Did you do a clinical differential 22 diagnosis in this case? 23

24 A. No. I did a pathologic differential

mucosa ulcerated, and ulcerated down to the point of 2 the mesh.

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Page 89

So it may have nothing to do with the mesh, and that's an important feature.

5 The patient may have had a viral 6 infection -- herpes, CMV, any other number of 7 viruses -- that ulcerated the mucosal surface, which then extended down into the soft tissue and then 8 9 that's how the mesh was eroded.

So I look at that and say, Okay. Well, I'm looking at the mucosa, and just like 11 Dr. Strauss did, recognize that the squamous mucosa

13 doesn't have any significant histopathologic change,

14 so that is not the etiology for the pain in this 15 example.

The other thing in my differential diagnosis would be, are there any sort of neoplastic proliferations that would have grown and moved the mesh, which clearly happens.

That happens in the uterus with women that have IUDs and they have a tumor and the tumor grows and the IUD comes out. It's not because the IUD came out on its own, it's because the tumor was growing.

So I look at the tissue, looking for

any sort of tumors or neoplasms, or anything that 3 could have grown clonally. There was nothing like

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that. Look for infections other than.

6 viruses like fungal infections. If she had been a 7 diabetic, she may have been predisposed to fungal 8 infections, which can be completely separate from 9 the mesh, and that could have caused the problems 10 that she was experiencing in that area and not from 11 the mesh.

12 You can have vasculitis where the 13 vessels become inflamed on their own and that's 14 something that's more often in women than men.

So that would not be inconsistent with, you know, a 53-year-old woman to find vasculitis in the tissue which can cause exquisite pain.

So that's the difference between a clinical and a pathologic differential diagnosis, is that clinicians can't do that because they're not looking under the microscope. They say, Here, I'm

22 taking this out; this is abnormal; it eroded through the mucosa, and my job is to rule out -- basically

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diagnosis.

Q. Okay. And what's the difference?

A. Well, a clinical differential diagnosis would be something that you would do clinically with a patient that presents with particular signs and symptoms.

Pathologically what I do is correlate the clinical differential diagnosis with what I'm seeing pathologically.

So I am -- I didn't examine the patient, I didn't take her history, I didn't think Oh, okay, well, her pain can be from this, from this, from this, or from this.

What I did is, I examined the pathologic specimen where a physician is taking out an area that is clearly grossly abnormal that was eroding through the vaginal wall -- you know, clearly migrated based on its location in the tissue, taking that out, submitting that to me, and my goal is to look at that and say, Okay, so what are the causes for, you know, her mesh erosion or pain, et cetera.

23 So mesh erosion can be because it 24 actually didn't migrate, but that the surface of the

23 (Pages 86 to 89)

Page 90

to evaluate why that happened. 1 2 And so that's what I did in this case

and what I would do in any case, whether I specifically say it or not, in a general pathology report that I would do in a hospital. That is what is the process of reviewing all of these specimens in pathology.

- 8 Q. Is a pathologic differential diagnosis more 9 robust than a clinical differential diagnosis?
- A. I wouldn't say one is more robust than the 10 11 other.
- 12 Q. Okay.

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A. I would say they both have their 13 complexities to them. 14

There are certainly a lot of diseases that I can diagnose under the microscope and there are certainly a lot of etiologies that a particular symptom can have. So I wouldn't say that one is necessarily more robust than the other, they're just different.

- 21 Q. Do you -- do you take into consideration the same things that a clinician would in a clinical 22 23 differential diagnosis?
- 24 A. Well, only in the sense that I'm taking

1 Q. What pain specifically are you correlating 2 to the specimen in this case?

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Page 93

- 3 A. Well, she reported pelvic pain and 4 dyspareunia. Both. So I would say both of those 5 would be consistent with my findings.
- 6 Q. Did you consider her prior Repliform sling 7 with the use of bone anchors in that?
  - A. Yes.
- 9 Q. Did you rule it out?
- 10 A. Yes.

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11 Q. How?

12 A. Because I -- from my recollection in this case from the operative report following that, they 13 had mentioned that everything was -- it was all 14 15 taken out.

And from my recollection from her deposition transcript, the quality of pain and the type of pain that she's describing is very different than any pelvic pain she had had before around the time that she initially had had that surgery.

21 Q. How did it change?

2.2 A. It was different type of pain.

23 I remember reading her deposition 24 transcript and reading her notes and coming to the

Page 91

into account that this is a symptom and I'm coming up with a list of possible etiologies that I could

3 identify histologically.

> But other than that, I would say that they're different in the sense that we're evaluating different parameters.

- Q. What role does the clinician's determination on reason for removal play in your pathologic differential diagnosis?
- 10 A. Well, it plays a role, because they are -we're at their mercy for them taking out the 11 diseased part of the tissue, or the tissue that they 12 13 are concerned about.

So we have to rely on clinical differential diagnosis to then perform a good pathologic differential diagnosis. Because if she's complaining of area -- in the vaginal area -- or sorry.

If she's complaining of pain or symptomatology in the vaginal area and then they do a skin biopsy from the posterior, you know, leg, well, that's not going to really help me.

23 So we have to rely on one another to 24 come to basically a consistent finding.

conclusion that it was described differently.

2 But I would have to, you know, go 3 through her deposition transcript to use the exact 4 words that she had used. I don't remember if she 5 had said a stabbing pain or something like that, but 6 it was described differently.

7 Q. Did you consider her opioid dependency in 8 coming to your conclusions in this case? 9

A. Absolutely.

10 MR. CURTIS: Object to the form of the 11 question.

BY MR. SNOWDEN:

Q. Did you rule those out -- rule that out? MR. CURTIS: Object to the form of the question.

A. Well, opioid -- whether she was dependent or casual use or abuse, whatever, would not in and of itself cause a scarring and inflammatory reaction around mesh, which is what I saw.

So had she complained of pain in a vaginal area and the clinicians were pointing to it and said, "Is this painful?"

23 And she said "Yes, that's exquisitely 24 painful."

24 (Pages 90 to 93)

	Page 94		Page 96
1	And then they took out that area and	1	mentioned mesh erosion, which again, there's
2	there was no mesh, no inflammation, then I would	2	evidence that there's no other cause of this in this
3	say, Hey, I don't have an explanation for it.	3	tissue that I examined, and female stress
4	But in this case, that's not and I	4	incontinence.
5	would say maybe it has to do with her reported use	5	Q. Thanks, Dr. Michaels.
6	of drugs.	6	MR. SNOWDEN: No further questions.
7	But in this case, that's not the case.	7	MR. CURTIS: Okay.
8	In this case, there was mesh that was clearly	8	(Proceedings concluded at 2:07 p.m.)
9	described as being irregular and ragged.	9	
10	Microscopically, I'm seeing scar	10	
11	tissue and what I'm showing on my microscopic slides		
12	is pores that have been filled with sclerotic	12	
13	hyalinized scar tissue, a prominent inflammatory	13	
14	reaction, and includes foreign-body-type giant	14	
15	cells, evidence of polypropylene degradation.	15	
16	So these are all things that if	16	
17	someone was just having pain from opioid use you	17	
18	wouldn't see all that, you would have a biopsy and	18	
19	there would be nothing.	19	
20	BY MR. SNOWDEN:	20	
21	Q. Okay. Is that what happened during the	21	
22	September 27th, 2012, surgery when the physician	22	
23	looking for mesh in the anterior vaginal didn't find	23 24	
24	any, broke scrub, talked to the patient's husband,	24	D 07
	Page 95		Page 97
1	and he for the first time told the doctor that that	1	
2	mesh had already been removed?		ERRATA
3	MR. CURTIS: Object to the form of the	2	
4	question.	4	PAGE LINE CHANGE
5 6	A. I would have to review that operative	5	THOE EINE CHANGE
7	report. I don't remember that. BY MR. SNOWDEN:	6	REASON:
8	Q. You don't recall that?	7	
9	MR. CURTIS: Object to the form of the	8	REASON:
10	question.	9	
11	A. I don't remember those details.	10	REASON:
12	I remember the pre-op I remember	11	
13	the pre-op diagnosis, and I remember, you know, the	12	REASON:
14	description of the surgery, but I don't know if it	13	DEAGON
15	had been removed prior I don't know who had	14 15	REASON:
16	removed it. I don't know if they submitted it for	16	REASON:
17	pathology. She obviously had a lot of different	17	
18	clinicians that she went to, so I would have to see.	18	REASON:
19	But that's not what I'm doing in this	19	
20	case. I'm describing what is clearly abnormal	20	REASON:
21	tissue.	21	
22	BY MR. SNOWDEN:	22	REASON:
23	Q. Was the pre-op diagnosis in this case pain?	23	
2.4	A No There was no mention of pain. It just	24	REASON:

25 (Pages 94 to 97)

Page 98		Page 100
1	1	J
2 ACKNOWLEDGMENT OF DEPONENT	2	I, Rebecca J. Callow, Registered Merit
3	3 R	eporter and Notary Public in and for the State of
4 I,, do		exas, hereby certify to the following:
5 hereby certify that I have read the	5	That the witness, PAUL J. MICHAELS, M.D.,
6 foregoing pages, and that the same is		as duly sworn by the officer and that the
7 a correct transcription of the answers 8 given by me to the questions therein		anscript of the oral deposition is a true record f the testimony given by the witness;
9 propounded, except for the corrections or	9	That the original deposition was delivered
10 changes in form or substance, if any,		)
11 noted in the attached Errata Sheet.	11	That a copy of this certificate was served
12	12 or	n all parties and/or the witness shown herein on
13	13 _	·
14	14	That pursuant to information given to the
15 PAUL J. MICHAELS, M.D. DATE		eposition officer at the time said testimony was
16 17		ken, the following the amount of time used by
18 Subscribed and sworn	17 ea	ach party at the time of the deposition:  M. Andrew Snowden (1h59m)
to before me this	10	Attorney for Johnson & Johnson and
	19	Ethicon, Inc.
19 day of, 20 20 My commission expires:	20	Danny L. Curtis (0h0m)
21		Attorney for Plaintiffs
	21	
22 Notary Public	22	
23 24	23 24	
Page 99		Page 101
		1490 101
1 IN THE UNITED STATES DISTRICT COURT 2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA	1	
3 CHARLESTON DIVISION 4	2	I further certify that pursuant to FRCP Rule
5 IN RE: ETHICON, INC., PELVIC ) Master File No.		0(f)(1) that the signature of the deponent:
REPAIR SYSTEM PRODUCTS ) 6 PRODUCTS LIABILITY LITIGATION ) 2:12-MD-02327	4   5 p:	[ ] was requested by the deponent or a
7 THIS DOCUMENT RELATES TO THE ) MDL 2327		arty before the completion of the deposition and is be returned within 30 days from date of receipt
FOLLOWING CASES IN WAVE 2 )		f the transcript. If returned, the attached
8 OF MDL 200: ) JOSEPH R. GOODWIN		Changes and Signature Page contains any changes and
9 Tamara Carter, et al. v. ) Ethicon, Inc., et al. ) U.S. DISTRICT JUDGE		ne reasons therefor;
10 Civil Action No. 2:12-cv-01661)	10	[ ] was not requested by the deponent or
11 Sandra Childress, et al. v. ) Ethicon, Inc., et al. )		party before the completion of the deposition.
12 Civil Action No. 2:12-cv-01564)	12	r · · · · · · · · · · · · · · · · · · ·
13 Marion Chrysler v. )	13	I further certify that I am neither
Ethicon, Inc., et al. ) 14 Civil Action No. 2:12-cv-02060 )	14 c	ounsel for, related to, nor employed by any of the
)		
1 15 Melissa Sanders, et al. v. )	15 pa	arties or attorneys to the action in which this
15 Melissa Sanders, et al. v. ) Ethicon, Inc., et al. ) 16 Giril Action No. 212 av. 01562 )		arties or attorneys to the action in which this roceeding was taken. Further, I am not a relative
Ethicon, Inc., et al. )  16 Civil Action No. 2:12-cv-01562 )	16 pr	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause,
Ethicon, Inc., et al.	16 pr 17 or 18 no	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause, or am I financially or otherwise interested in the
Ethicon, Inc., et al. )  16 Civil Action No. 2:12-cv-01562 )  17 Ana Sierra, et al. v. )	16 pr 17 or 18 no 19 or	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause,
Ethicon, Inc., et al. )  16 Civil Action No. 2:12-cv-01562 )  17 Ana Sierra, et al. v. ) Ethicon, Inc., et al. )  18 Civil Action No. 2:12-cv-01819 )  19 Toni Hernandez v. )	16 pr 17 or 18 no 19 or 20	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause, or am I financially or otherwise interested in the
Ethicon, Inc., et al. )  16 Civil Action No. 2:12-cv-01562 )  17 Ana Sierra, et al. v. ) Ethicon, Inc., et al. )  18 Civil Action No. 2:12-cv-01819 )  19 Toni Hernandez v. ) Ethicon, Inc., et al. )  20 Civil Action No. 2:12-cv-02073 )	16 pi 17 or 18 no 19 or 20 21	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause, or am I financially or otherwise interested in the
Ethicon, Inc., et al. )  16 Civil Action No. 2:12-cv-01562 )  17 Ana Sierra, et al. v. ) Ethicon, Inc., et al. )  18 Civil Action No. 2:12-cv-01819 )  19 Toni Hernandez v. ) Ethicon, Inc., et al. )  20 Civil Action No. 2:12-cv-02073 )  21	16 pi 17 oi 18 no 19 oi 20 21 22	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause, or am I financially or otherwise interested in the
Ethicon, Inc., et al. )  16 Civil Action No. 2:12-cv-01562 )  17 Ana Sierra, et al. v. ) Ethicon, Inc., et al. )  18 Civil Action No. 2:12-cv-01819 )  19 Toni Hernandez v. ) Ethicon, Inc., et al. )  20 Civil Action No. 2:12-cv-02073 )	16 pi 17 or 18 no 19 or 20 21	roceeding was taken. Further, I am not a relative r employee of any attorney of record in this cause, or am I financially or otherwise interested in the

26 (Pages 98 to 101)

	Page 102	
1	1350 102	
2		
3		
4	SUBSCRIBED AND SWORN TO under my hand and	
5	seal of office on this the day of	
6		
7		
8 9		
9 L0	Rebecca J. Callow, RMR, CRR, RPR	
L1	Notary Public, Travis County, Texas	
L2	My Commission No. 12955701-3	
.3	Expires: 09/12/2017	
.4		
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7.8		
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